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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,674	02/28/2002	Johannes Bartholomaeus	148/50986	2545

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/084,674	Applicant(s) BARTHOLOMAEUS ET AL.	
	Examiner Simon J. Oh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-67 is/are pending in the application.
- 4a) Of the above claim(s) 10,13,14,16,19,20,22-29,33-54 and 59-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11,12,15,17,18,21,30-32,55-58 and 62-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's response, petition for extension of time, and request for continued examination, all received on 25 September 2006.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 September 2006 has been entered.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1 and 3-67 under 35 U.S.C. 112, first paragraph, for enablement, is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-5, 15, 17, 18, 21, 30-32 and 62-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Burnside *et al.* (U.S. Patent No. 6,322,819)

The Burnside *et al.* patent discloses a pharmaceutical dosage form comprising an enteric coating (See Abstract). The disclosed compositions contain one or more amphetamine salts and may optionally have an additional protective layer (See Column 3, Lines 15-38). Suitable enteric polymers include EUDRAGIT® NE30D, while suitable polymers for use in the protective layer include EUDRAGIT® RS30D and RL30D (See Column 7, Line 56 to Column 8, Line 67). The composition may be formulated into beadlets that may be used to make capsules, or the composition may be incorporated into a tablet (See Column 9, Lines 16-59).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 3-9, 11, 12, 15, 17, 18, 21, 30-32, and 55-58 under 35 U.S.C. 103(a) as being unpatentable over Oshlack *et al.* in view of Sackler *et al.* is hereby withdrawn.

Claims 1, 3-9, 11, 12, 15, 17, 18, 21, 30-32, 55-58 and 62-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack *et al.* (PCT Publication No. WO 99/01111)

The Oshlack *et al.* reference discloses a stabilized sustained release solid oral dosage form, which includes an effective amount of tramadol or a pharmaceutically acceptable salt thereof, dispersed in a material of a hydrophobic material (See Abstract). Suitable pharmaceutically acceptable salts of tramadol for use are those conventionally known in the art, such as pharmaceutically acceptable acid addition salts (See Page 11, Lines 3-5). Although tramadol hydrochloride is specifically mentioned, the reference suggests the use of other, or tramadol HCL would be the only salt discussed throughout the specification. The reference also teaches that the sustained release matrix includes a hydrophobic polymer that comprises one or more alkylcelluloses, particularly ethylcellulose (See Page 15, Lines 13-16). Additionally, the reference teaches that the sustained release preparation can be presented as granules, multi-particulates, capsules, or preferably tablets (See Page 176, Lines 22-23). Furthermore, tablets may be covered with a hydrophobic polymer film coating, such as an acrylic polymer, including but not limited to acrylic acid and methacrylic acid copolymers (See Page 18, Lines 14-17).

The Oshlack *et al.* reference does not explicitly disclose the use of mixtures of salts of tramadol. However, according to *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." As this court explained in *In re Crockett*, 126 USPQ 186, 188 (CCPA 1960), the idea of combining them flows logically from their having been individually taught in the prior art. Therefore, it would be obvious to one of ordinary skill in the art to take one embodiment of the disclosed invention, containing a tramadol salt and combine it with another embodiment of the disclosed invention containing a different tramadol salt in order to produce a third

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embodiment containing a mixture of both tramadol salts. All of the three aforementioned compositions are to be used for the same functional purpose, and as such the production of the aforementioned third embodiment was well within the range of knowledge of one of ordinary skill in the art at the time the instantly claimed invention was made. Hence, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 25 September 2006 have been fully considered but they are moot with respect to the prior art rejection previously set forth, in view of the new prior art set forth above. Applicant's arguments with respect to the scope of enablement rejection of record have been fully considered, but they are not found to be persuasive.

The examiner does not reject the claims on the basis that no embodiments disclosed by the instant specification are enabled. As previously set forth by the examiner, tramadol and promethazine are considered properly enabled by the instant specification. However, the examiner does not find proper enablement for all other embodiments that are conceivably encompassed by the scope of the instant claims.

The applicant begins by arguing that salt formation is not unpredictable, and the examiner does not dispute this statement. However, the applicant's instantly claimed invention is not directed to the formation of salts of pharmaceutical agents, but to a controlled release composition containing at least two salts of any pharmaceutical agent, and thus far, the examiner has not seen sufficient evidence that the applicant has in fact possessed the necessary knowledge to make and use the full scope of what is encompassed by what has been claimed.

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Next, the applicant argues that the examiner doubts the veracity of what has been disclosed by the instant specification. That is not the issue here. The issue is a lack of evidence that demonstrates enablement over the full scope of the instantly claimed invention.

The applicant then argues that the scope of enablement must only bear a reasonable correlation to the scope of the claims. However, on the basis of reasonable correlation, the instant specification lacks sufficient evidence of this correlation, as will be explained below.

Finally, the applicant argues that the nature of the active substances is irrelevant so long as the active substances are salts which fulfill the requirement with respect to solubility, and that the breadth of this discovery justifies the breadth of the claims. The examiner cannot agree with this. The instant specification does not satisfactorily address issues relating to the bioavailability of active agents beyond the solubility properties of pharmaceutical agents in such a way that one of ordinary skill in the art could practice the full scope of the instantly claimed invention without undue experimentation. Such issues include, for example, particle sizes of active agents, the presence or absence of solubilizing excipients, and compatibility of the active agents with controlled release excipients. That one of ordinary skill in the art is primarily required to choose two or more salts of an active agent of differing solubilities in order to best practice the instantly claimed invention apart from the aforementioned issues without undue experimentation is something that is not properly supported by the instant specification. The examiner maintains this rejection because the guidance found the instant specification that allows one of ordinary skill in the art to practice the full scope of what is encompassed by the claims is simply lacking, not because the examiner arbitrarily presumes that the instant specification lacks veracity. Thus, the scope of enablement rejection of record will be maintained.

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Correspondence

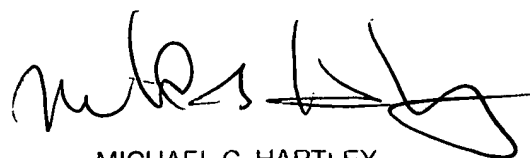
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sj0



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER